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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/839,752	04/19/2001	Victor J. Dzau	50025/003002	2781

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EXAMINER

MARVICH, MARIA

ART UNIT PAPER NUMBER

1636

DATE MAILED: 06/05/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/839,752

Applicant(s)

DZAU ET AL.

Examiner

Maria B. Marvich

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 13-16 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 13-16 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 12 October 2001 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 3.
- 4) ☒ Interview Summary (PTO-413) Paper No(s). 8.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

DETAILED ACTION***Specification***

The disclosure is objected to because of the following informalities: The specification contains tables on pages 6-7 and page 10-11 that are not suitable for publication as part of the specification. Tables must be deleted from specification and submitted as drawings.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 13-16 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 8 of copending Application No. 08/524, 206 in view of Mudryj *et al.* (EMBO 9(7) pp. 2179-2184, 1990).

Applicants claim a method for inhibiting proliferative lesion formation in a blood vessel through the introduction of dsDNA that comprises a sequence that is specific for binding to transcription factor E2F (E2F decoy). In its broadest sense, the method reads on treatment of humans or mammals.

Application 08/524, 203 claims a method for treating a mammalian to prevent restenosis by introduction of dsDNA at the site of a vascular lesion. Said dsDNA is characterized by

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having a sequence specific for binding to a transcription factor necessary for the transcription of at least one gene, where the transcription product of said gene is necessary for proliferation of said cells. 08/524, 206 do not claim use of dsDNA specific for the binding to E2F for the treatment of restenosis.

Mudryj *et al* teach that E2F is a transcription factor with a role in activation of transcription of genes necessary for cell proliferation (page 2180, column 2, line 1-8). As well, they suggest an essential role for E2F in regulating proliferation (page 2182, column 2, line 14-19). A person of ordinary skill in the art would have been motivated to choose to inhibit proliferation with E2F dsDNA that has sequence specific binding to E2F due to the essential role that E2F plays in proliferation-dependent signal transduction. It would have been obvious to someone of skill in the art to inhibit E2F function in order to inhibit restenosis, which is proliferation of vascular smooth muscle cells. Given the teachings of the cited art and the level of skill of the ordinary skilled artisan at the time of the applicant's invention, it must be considered that said ordinary skilled artisan would have had a reasonable expectation of success in practicing the claimed invention.

This is a provisional obviousness-type double patenting rejection.

Response to Amendment

The Remarks filed under 37 CFR 1.10 filed 4/19/2001 is insufficient to overcome the rejection of claims 13-16 based upon Double Patenting as set forth in this Office action because: the rejection is not solely based upon the prior art and the skilled artisan's ability to treat

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infrainguinal vein grafts. The claims in the instant application are rejected due to double patenting issues with parent application 08/524, 206.


Arguments by Susan M. Michaud for enablement of E2F decoys for the inhibition of proliferative lesion formation in human blood vessels are presented. As reference to this is provided the results from human clinical trials in which E2F decoys are introduced into human infrainguinal vein grafts.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Maria B Marvich, PhD whose telephone number is (703) 605-1207. The examiner can normally be reached on M-F (6:30-3:00).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Remy Yucell, PhD can be reached on (703) 305-1998. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4242 for regular communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to Patent analyst Kay Pinkney whose telephone number is (703) 305-3553.


Maria B Marvich, PhD
Examiner
Art Unit 1636

May 31, 2002

DAVID GUZO
PRIMARY EXAMINER
